IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Group No.: 1644

David WALLACH et al

Examiner: P. Gambel

Appln. No.: 08/476,862

Filed: June 7, 1995

For: TNF LIGANDS

Atty. Docket: WALLACH=12A

DECLARATION OF BIOLOGICAL MATERIAL DEPOSIT

Honorable Commissioner for Patents Washington, D.C. 20231

Sir:

Yeda Research and Development Co. Ltd., a corporation having a principal place of business at Rehovot 76100, Israel, (hereinafter "Yeda") hereby certifies that it is the depositor of the biological material referred to herein and is also the assignee of the entire right, title and interest of the above-identified United States Patent application by virtue of assignments from the inventors of the above-identified United States Patent application. Assignments from four of the five inventors were recorded March 19, 1996, at Reel 7853, Frame 0762, copies of which are attached hereto, and an assignment from the fifth inventor (Hartmut Engelmann) was submitted for recordation on October 11, 2000, a copy of which is also attached hereto. The attached copies establish a chain of title from each of the inventors to Yeda. The undersigned (whose title is supplied below) is empowered to sign this document on behalf of the depositor/assignee.

In re Appln. No. 2476,862 Declaration of Biological Culture Deposit

2. The following biological material, referred to in the specification of this application, has been deposited and has received the following accession number(s) by the depository:

Monoclonal antibody 67 strain

I-1368

accession number

- 3. The name and address of the depository is:

  Collection National de Cultures de
  Microorganismes (CNCM), Institut Pasteur
  25, rue de Docteur Roux,
  75724 Paris Cedex 15, France.
- 4. The above deposit of monoclonal antibody 67 was made on October 11, 1993, which was before the filing date of Israeli application 107,267 filed October 12, 1993. original deposit was a non-Budapest deposit as the depository at that time did not accept hybridomas under the Budapest Treaty. However, CNCM acquired status of international depository authority for hybridomas on January 31, 1996. The originally deposited material was converted to a Budapest Treaty Deposit by request received on December 17, 1996. A copy of the International Receipt Form, dated March 31, 2000, acknowledging this deposit as a Budapest Treaty deposit is attached hereto. The deposit date of October 11, 1993, was after the filing date of the first application upon which reliance is made for this monoclonal antibody, i.e., Israeli application 94,039 filed April 6, 1990. A verified statement pursuant to 37 CFR 1.804(b) will be filed in due course, stating that the biological

material which was deposited is a biological material specifically identified in the application as filed.

- 5. The biological material deposited is capable of self-replication, either directly or indirectly, and
  - XXX The originally deposited biological material described above has been accepted under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter Budapest Treaty) and therefore the filing of a viability statement is unnecessary (37 CFR 1.807(b)).
  - XXX Statements that the biological material deposited with the above named depository was viable and was capable of reproduction on the date of the original deposit, as well as at the time of conversion to a Budapest Treaty deposit, are attached. Such are executed by:

(complete a, b or c below)

- a.  $\underline{XX}$  the depository
- b. \_\_ the applicant
- c. \_\_ a competent third party
- 6. With respect to the permanence of the biological material deposit:
  - XXX The depository is an official depository in accordance with the Budapest Treaty and the deposit of the biological material described above has been accepted under the Budapest Treaty such that samples will be

In re Appln. No. 2/476,862 Declaration of Biological Culture Deposit

available beyond the enforceable life of the patent for which the deposit was made.

The contract with the above-mentioned depository with respect to the deposited biological material provides that the depository will afford permanence of the deposit for at least 30 years and at least 5 years after the most recent request for the furnishing of a sample of the deposit was received by the depository, samples being available beyond the enforceable life of the patent for which the deposit was made.

I affirm that should the depositor be notified by the depository that it either cannot furnish samples thereof or can furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification, depositor will proceed in accordance with 37 CFR \$1.805.

7. With respect to availability of the biological material, I affirm that the deposit has been made under conditions that assure that (a) access to the deposit will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR \$1.14 and 35 USC \$122, and (b) subject to 37 CFR \$1.808(b), all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

In re Appln, No. 08/476,862 Declaration of Biological Culture Deposit

7. I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

YEDA RESEARCH AND DEVELOPMENT CO. LTD.

Paulina Ben-Ami, Vice President
Type or Print Name of Person Signing

12 October 2000

Paulina Blu. Am; signature

Inventor
Assignee of Complete Interest
Person Authorized to Sign on
Behalf of the Depositor/Assignee

(complete the following if applicable)

YEDA RESEARCH AND DEVELOPMENT CO. LTD. Type Name of Depositor/Assignee

P.O. Box 95, Rehovot 76100, ISRAEL Address of Depositor/Assignee

Title of Person Authorized to Sign on Behalf of Depositor/Assignce:

AGREEHEN 25 AUGUST 1978, AS AVENOCO DN 4 OCTOBER 1982, BETWEEN GURDEAM PATENT ORGANISATION AND THE COLLECTION NATIONALE DE CULTURES DE HICROORGANISMES (C.N.C.M.). INSTITUT PASTEUR, PARIS, CONCERNING THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE UNDER RULES 28 AND 288 OF THE EUROPEAN PATENT CONVENTION.

TOO DISCOUR 1000000111000000111111100000000

## INTERNATIONAL PORH

Copy of the Original Receipt

COLLICIION NATIONALE CULTURES Dē.

10

YEDA RESEARCH AND DEVELOPMENT Co.Ltd. at the Welzmann Institute P.O. Box 95
REHOVOT 76100 ISRAEL
NAME AND ADDRESS
OF DEPOSITOR

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSYTTIES by Issued pursuant to suit a the Point H.(a) by the GENER INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page CNCM, Director

		august 10, 2000 Micros OF
I. IDEA	TYTCATION OF THE HICROORGANISH	Tim pas
Identific DEPOSITOR	ation reference given by the	ACCORDION NUMBER GIVEN BY EN- INTERNATIONAL DEPOSITARY AUTHORITY L'ORIGINAL
67		I - 1368
II. BCIE	NTIPIC DESCRIPTION AND/OR PROPOSE	ED TAXONOMIC DESIGNATION
The micro	organism identified under I above	• was accompanied by:
	scientific description	
a	proposed texonomic designation	
(Hark With	a cross where applicable;	
YII. REX	EIPT AND ACCEPTANCE	
	rnational Depositary Authority acrecived by it on October 11,	ocepts the microorganism identified under I above. (date of the original deposit) 1993
IV. RECE	IPT OF REQUEST FOR CONVERSION	·
a request	organism identified under I above y Authority on (d to convert the original deposit ved by it on	e was received by this International date of the original deposit) and to a deposit under the Budgest mbilateral Agreement (date of receipt of request for conversion)
V. 1876	UNATIONAL DEPOSITARY AUTHORITY	
Name I	CNCM Collection Nationals de Cultures de Microorganismes	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):
Address	INSTITUT PASTEUR 28, Rue du Dooteur Roux F-75724 PARIS CEDEX 16	Dato: November 24, 1993 Sering

Porm BP/4 (sole page)

Mme Y. CERISIER Administrative Director of the CNCM AGREEMENT OF 25 AUGUST 1978, AS AMENDED ON 4 OCTOBER 196. BETWEEN THE EUROPEAN PATENT ORGANISATION AND THE COLLECTION NATIONALE DE CULTURES DE MICROORGANISMES (C.N.C.M.), INSTITUT PASTEUR, PARIS, CONCERNING THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE UNDER RULES 28 AND 28a OF THE EUROPEAN PATENT CONVENTION.

DODAFEST TREATY ON THE INTERNATIONAL

RESSOUTTION OF THE DETOSIT OF TREATMONGARMISTS

FOR THE RUPPOCES OF PARENT PROSPECTORS

INTERNATIONAL FORM

TO

Mr Enrica DRAGHI
INTER-LAB Ltd.
Science-Based Industrial Park
Kiryat Weizmann,
NESS ZIONA
76110,ISRAEL

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS ISSUED VIABILITY STATEMENT issued pursuant to Puls 10.2 by the INTERNATIONAL DEPOSITARY AUTHORITY identified on the following page

I. DEPO:	SITOR	II. IDENTIFICATION OF THE MICROORGANISM			
Name: Address:	YEDA RESEARCH AND DEVELPOMENT Co.Ltd. at the Weizmann Institute of Science P.O. Box 95 REHOVOT 76100 ISRAEL	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:    - 1368			
III. VIABILITY STATEMENT					
The viabi	lity of the microorganism identified un	der II above was tested			
On 3	October 12, 1993	<ol> <li>On that date, the said microorganism was</li> </ol>			
viable					
no l	longer viable				

Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).

Point 24.b)(i) and (ii)

In the cases referred to in Puls 10.3(a)(ii) and (til), refer to the most recent viability test.

Mark with a cross the applicable box.

IV.	CONDITIONS	UNDER WHICH	THE VI	[ABILITY	TEST	HAS	BEEN	PERFORMED 4			
				,							
		·		<del></del>				· <del></del>			
v	V. INTERNATIONAL DEPOSITARY AUTHORITY										
Name Addre	ess:	CNCM Collection Nationale de Cultures de Microorganismes INSTITUT PASTEUR			i	to re	ture(s) of per present the In rity or of aut	ternational	Depositary		
	2 <sup>5</sup>	8, Rue du Docteui -75724 PARIS CEI RANCE					Date:	Done in Pari	s on Novem	ber 24, 1993	}

Fill in if the information has been requested and if the results of the test were negative.

Simona OZDEN Scientific Advisor of the CNCM for the Cell-lines

Yvanne CERISIER

Administrative Director of the CNCM

Form BP/9 (second and last page)

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

at the Weizm P.O.Box 95 Rehovot 761	ch and Development Co. LtdINTERNAT: nann Institute of Science identific	Certified  IN THE CASE OF AN ORIGINA COPPE OF the Original Receipt arsuant to Rule 7.1 by the HONAL DEPOSITARY AUTHORITY and at the bottom of this page RANGHALE CULTURES MARCH 31, 2000 M			
i. IDENTII	FICATION OF THE MICROORGANISM				
DEPOSITOR :	on reference given by the	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:			
II. SCIENTI	IFIC DESCRIPTION AND/OR PROPOSED TAXO	NOMIC DESIGNATION			
The microorga	nism identified under I above was ac	companied by :			
a sc	ientific description				
a pr	oposed taxonomic designation				
(Mark with a	cross where applicable)				
III. RECEIPT	AND : ACCEPTANCE				
This Internat	ional Depositary Authority accepts theired by it on 31 January 1996	he microorganism identified under I above, (date of the original deposit) <sup>1</sup>			
IV. RECEIPT OF REQUEST FOR CONVERSION					
Depositary Au	convert the original deposit to a dep	(date of the original deposit) and			
V. INTERNA	TIONAL DEPOSITARY AUTHORITY				
Name :	CNCM Collection Nationale de Cultures de Microorganismes	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):  Georges WAGENER Director, CNCM			
Address :	INSTITUT PASTEUR 28, Rue du Docteur Roux F-75724 PARIS CEDEX 15	Date: 31 March 2000 (pl/agmm)			

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of  $^{\prime}$  international depositary authority was acquired.

## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO:

Mr. Henry Einav,
Director of Corporate Patent Department,
Inter-Lab Ltd,
Science-based Industrial Park,
Kiryat Weizmann,
Ness-Ziona 76100,
Israel
NAME AND ADDRESS OF THE PARTY
TO WHOM THE VIABILITY STATEMENT
IS ISSUED

VIABILITY STATEMENT issued pursuant to Rule 10.2 by the INTERNATIONAL DEPOSITARY AUTHORITY identified on the following page

II. IDENTIFICATION OF THE MICROORGANISM			
Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:			
Date of the deposit or of the transfer $^{1}$ :			
31 January 1996 `			
II above was tested t date, the said microorganism was			
viable			

- I Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a)(ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV.	CONDITIONS	UNDER WHICH THE VIABILITY TE	ST HAS I	BEEN PERFORMED 4
	·			
٧.	TNTERNATION	AL DEPOSITARY AUTHORITY		
Name	:	CNCM Collection Nationale de Cultures de Microorganismes		Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):
Addre	ss :	INSTITUT PASTEUR 25, Rue du Docteur Roux 75724 PARIS CEDEX 15 FRANCE		Georges WAGENER Director, CNCM  Date: 31 March 2000

4 Fill in if the information has been requested and if the results of the test were negative.